HFEA Executive Licensing Panel Meeting

22 August 2014

Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF

Minutes – Item 2

Centre 0149 – (Royal Derby Hospital) – Interim Inspection Report

Members of the Panel: Juliet Tizzard – Director of Strategy & Corporate Affairs (Chair) Hannah Verdin – Head of Regulatory Policy David Moysen – Head of IT	Committee Secretary: Dee Knoyle Observing: Sam Hartley – Head of Governance & Licensing

Declarations of Interest: members of the Panel declared that they had no conflicts of interest in relation to this item.

The Panel had before it:

- HFEA Protocol for the Conduct of Meetings of Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree)
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009.
- Guidance on periods for which new or renewed licences should be granted
- Standing Orders and Instrument of Delegation
- Indicative Sanctions Guidance
- HFEA Direction 0008 (where relevant), and any other relevant Directions issued by the Authority
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Consideration of Application

1. The Panel noted that the Royal Derby Hospital is located in central Derby and has held a licence with the HFEA since July 1995. The centre has been licensed for treatment (insemination using partner / donor sperm) and storage, since 2007. The centre re-commenced donor insemination (DI) treatment in December 2013, having stopped in 2008 due to a shortage of donor sperm. The centre is a satellite IVF service provider for CARE Nottingham (centre 0101).

2. The Panel noted that the centre is currently on a four-year licence, due to expire on 31 October 2016.

3. The Panel noted that the inspection took place on 28 May 2014.

4. The Panel noted that HFEA-held register data for the year ending 2013 show the centre reported 237 cycles of partner insemination with 24 pregnancies. This equates to a pregnancy rate of 10% which is consistent with the national average. The Panel noted that in the 12 months to April 2014, the centre had provided 5 cycles of DI treatment. In relation to activity levels this is a small centre.

5. The Panel noted that one of the 24 pregnancies reported in 2013 was a multiple pregnancy. The data had been validated and is consistent with the national average multiple pregnancy rate.

6. The Panel noted that at the time of inspection there were three major areas of non-compliance identified. The Panel noted that since the inspection the Person Responsible has fully implemented one of the recommendations and is committed to fully implement the outstanding recommendations within the prescribed timescales.

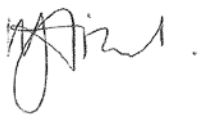
7. The Panel acknowledged the positive comments made by patients in relation to their experience of the centre.

8. The Panel noted that the Inspectorate recommends the continuation of the centre's licence.

Decision

9. The Panel had regard to its decision tree and was satisfied that the centre was fit to have its Treatment (insemination using partner/donor sperm) licence continued.

10. The Panel approved the Inspectorate's recommendation to continue the centre's licence with no additional conditions.



Signed: Date: 5 September 2014

Juliet Tizzard (Chair)

Interim Licensing Report

Centre name: Royal Derby Hospital
Centre number: 0149
Date licence issued: 1 November 2012
Licence expiry date: 31 October 2016
Additional conditions applied to this licence: None
Date of inspection: 28 May 2014
Inspectors: Mrs Lisa Beaumont (Lead), Dr Douglas Gray
Date of Executive Licensing Panel: 22 August 2014

Purpose of the report

The Human Fertilisation and Embryology Authority (HFEA) is the UK's independent regulator of the fertility sector. The HFEA licenses centres providing in vitro fertilisation (IVF) and other fertility treatments and those carrying out human embryo research.

Licensed centres usually receive a licence to operate for up to four years and must, by law, be inspected every two years. The full inspection prior to a licence being granted or renewed assesses a centre's compliance with the law and the HFEA's Code of Practice (CoP) and Standard Licence Conditions (SLC).

This is a report of a short notice interim inspection together with our assessment of the centre's performance based on other information. We do this at the mid-point of the licence period. For 2012-14 the focus of an interim inspection is:

- **Quality of service**: the quality of service provided by a centre, including its success rates and performance in reducing multiple births – the biggest single risk of IVF.
- **Patient experience**: it is considered crucial that the experiences of service users feed into any evaluation of a centre's performance.

We also take into account the centre's own assessment of its service; the progress made in implementing the actions identified at the last inspection; and our on-going monitoring of the centre's performance.

The report represents a mid-term evaluation of a centre's performance based on the above. The aim is to provide the Authority's Executive Licensing Panel with information on which to make a decision about the continuation of the licence.

Summary for the Executive Licensing Panel

This report has enabled the inspection team to form a conclusion on the continuation of the centre's licence.

The inspection team recommends the continuation of the centre's licence. In particular we note:

- the positive patient feedback comments received.

The Executive Licensing Panel is asked to note that the report makes recommendations for improvement in relation to three 'major' areas of non-compliance. Since the inspection, the Person Responsible (PR) has provided evidence that the following recommendation has been fully implemented:

'Major' areas of practice that require improvement:

- The PR should assure himself that the two donor sperm samples in storage are stored within the terms of their individual consents.

The PR has given a commitment to complete the remaining actions to implement the following recommendations within the specified timescales:

'Major' areas of practice that require improvement:

- The PR should ensure that patient / partner consents to disclosure of identifying information to researchers are reported accurately to the HFEA, for patients undergoing donor insemination.

- The PR should ensure that, wherever possible, only CE marked medical devices are used.

Information about the centre

The Royal Derby Hospital is located in central Derby and has held a licence with the HFEA since July 1995. The centre has been licensed for treatment (insemination using partner / donor sperm) and storage, since 2007. The centre re-commenced donor insemination (DI) treatment in December 2013, having stopped in 2008 due to a shortage of donor sperm. The centre is a satellite IVF service provider for CARE Nottingham (centre 0101).

The centre provided 237 cycles of IUI treatment in the 12 months to December 2013. The centre has provided 5 cycles of DI treatment in the 12 months to April 2014. In relation to activity levels this is a small centre.

A change of Person Responsible (PR) from Mr Joe Darne to Dr Kannamannadiar Jayaprakasan was approved by the Executive Licensing Panel (ELP) in June 2012.

A change of Licence Holder (LH) to Mr Saad Amer was approved by the ELP in July 2012.

Details of Inspection findings

Quality of Service

Each interim inspection focuses on the following themes: they are very important indicators of a centre's ability to provide high quality patient care and to meet the requirements of the law.

Pregnancy outcomes[1]

HFEA held register data for the year ending 2013 show the centre reported 237 cycles of partner insemination with 24 pregnancies. This equates to a pregnancy rate of 10% which is consistent with the national average.

Multiple births[2]

The single biggest risk of fertility treatment is a multiple pregnancy.

The centre reported 24 pregnancies in 2013, and one of these was a multiple pregnancy. The data has been validated and is consistent with the national average multiple pregnancy rate.

Witnessing

Good witnessing processes are vital in ensuring there are no mismatches of gametes or embryos and that identification errors do not occur. There was no licensed activity in the laboratory on the day of inspection, so witnessing procedures could not be observed, however witnessing procedures for IUI and donor insemination (DI) were discussed alongside the relevant forms. The inspection team are satisfied that the centre's procedures for witnessing are in accordance with HFEA requirements. The inspection team was able to review witnessing records that were present in the patient records and concluded that records of manual witnessing are maintained.

[1] The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems. Centre success rates are considered statistically different from the national averages, and multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$.

Consent: Disclosure to researchers

A patient providing informed consent is one of the most important principles in healthcare. Since 1 October 2009, the HFEA has been able to release patient-identifying information held by the HFEA to researchers if patients give their permission. Patients are asked to give their consent to the disclosure of this information and this is recorded in their records and the HFEA is notified of their decision through the electronic data interface (EDI) system. It is important that the reporting through EDI is accurate so that patient information is not disclosed without consent.

The inspection team noted that the full CD consent form is being used for IUI patients, and the records of those patients reviewed on inspection contained completed consents to disclosure to researchers. The HFEA does not hold information, including records of intentions relating to consent to disclosure to researchers, about patients receiving partner IUI. The PR is advised to use the 'consent to disclosure - general purpose' version, for these patients.

The inspection team was only able to review one set of donor insemination patient notes, and a discrepancy was identified; the centre had inaccurately reported the patients consent decision as documented in their consent to disclosure to researchers form to the HFEA (see recommendation 3).

Consent: To the storage of cryopreserved material

The centre has two donor sperm samples, supplied by centre 0162, currently in storage. On the day of the inspection the centre could not provide evidence of the written effective consent for the storage and use of the two donor sperm samples. As a consequence, this adversely impacts on the centre's ability to ensure that the samples are stored and used within the terms of the donor's consent (see recommendation 1).

Staffing

Having the right numbers of staff, competent to carry out highly technical work in a non-pressured environment is important in infertility services.

Staffing levels observed in the course of the on-site inspection appeared to be suitable for the activities being carried out: patients were seen promptly on arrival and the atmosphere in the clinic appeared calm at all times.

Patient experience

During the inspection visit we spoke to two patients who provided feedback on their experiences and observed interactions between centre staff and patients. A further five patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive with five of the individuals providing written feedback to the HFEA commenting that they have compliments about the care that they received.

On the basis of this feedback and observations made in the course of the inspection it was possible to assess that the centre:

- has respect for the privacy and confidentiality of patients in the clinic;
- gives prospective and current patients, accessible and up-to-date information to enable them to make informed decisions;

- provides a friendly and supportive service with continuity of care for patients.

Monitoring of the centre's performance

In addition to commenting on evidence gathered on the inspection it is important to report on the centre's performance since the granting of the licence based on other evidence available to us.

Compliance with HFEA standard licence conditions

From the information submitted by the centre in their self assessment questionnaire and from observations during the visit to the centre, the inspection team identified the following non-compliances:

It was observed on inspection that the following medical devices in use were not CE marked: pipettes and conical test tubes (see recommendation 2).

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in May 2012 recommendations for improvement were made in relation to four major non-compliances and three "other" areas on non-compliance.

The PR provided information and evidence that all the recommendations had been fully implemented.

On-going monitoring of centre success rates

No RBAT alert letters have been sent to this centre during the last 12 months.

Provision of information to the HFEA

Clinics are required by law to provide information to the HFEA about all licensed fertility treatments they carry out. The centre's register submissions are compliant with HFEA requirements.

Annex 1

Areas of practice that require the attention of the Person Responsible

The section sets out matters which the Inspection Team considers may constitute areas of non compliance. These have been classified into critical, major and others. Each area of non-compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, Directions or the Code of Practice, and the recommended improvement actions required are given, as well as the timescales in which these improvements should be carried out.

‘Critical’ area of non compliance

A ‘critical’ area of non compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or child who may be born as a result of treatment services. A ‘critical’ area of non-compliance requires immediate action to be taken by the Person Responsible.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
None			

‘Major’ area of non compliance

A ‘major’ area of non compliance is a non critical area of non compliance:

- which poses an indirect risk to the safety of a patient, donor, embryo or child who may be born as a result of treatment services
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties
- a combination of several ‘other’ areas of non-compliance, none of which on their own may be major but which together may represent a major area of non-compliance.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
1. On the day of the inspection the centre could not provide evidence of the written effective consent for the storage and use of the two donor sperm samples in storage. As a consequence, this adversely impacts on the centre's ability to ensure that the samples are stored within their consented storage period and that any restriction on their use is known and adhered to. (Schedule 3, 8(1) HF&E Act).	The PR should assure himself that the two donor sperm samples are stored within the terms of their individual consents, and provide the HFEA with evidence of this by 14 July 2014.	The donor samples are stored within the terms of the individual consents. We contacted the Nottingham hospitals for the donors' consent forms. while they are happy to provide the consents form it will be anonymous with out any information. Regarding the expiry dates of the smaple, they are all written on the straw supplied. More over, the terms of the consent and storage period are all implicit within the 3rd party agreement.	The centre has confirmed that it now has correspondence confirming that valid consents are in place, from centre 0162 for the two sperm donor samples. A redacted copy of the consents (to maintain donor anonymity), will also be kept in the patient’s records. No further action required.
2. It was observed on inspection that the following medical devices in use were not CE marked:	The PR should ensure that, whenever possible, only CE marked medical devices are	We shall try our best to get CE marked devices as much as possible. However, we are	The Executive acknowledges the PR’s commitment to

o pipettes and o conical test tubes. (SLC T30)	used. By 28 August 2014, the PR should advise the centre's inspector whether CE marked alternatives are available, and if so provide a timeframe within which they expect that this change can be made.	struggling to get some CE marked devices. Andrea Blair, our andrologist have enqired other labs in the country and could not find a source for those devices (conical flask) with CE marked	source CE marked devices, and will follow up this action as part of the post inspection monitoring process.
3. A discrepancy was found with one patient undergoing donor insemination treatment, between completed patient disclosure consents and the related consent data submitted for inclusion in the HFEA register. (Chair's letter CH (10)05 and supplementary guidance and General Directions 0007).	The PR is required to ensure that the data submission identified as being incorrect is corrected immediately. Given the low number of DI cycles completed to date, and expected in the near future, the PR should advise the HFEA of any steps taken to ensure that future submissions of CD consents to the HFEA are accurate. This recommendation should be implemented by 28 August 2014.	The discripancy have been corrected already	The Executive acknowledges that the data discrepancy has been corrected. The PR is reminded to advise the HFEA of any steps taken to ensure that future submissions of CD consents to the HFEA are accurate. This action will be followed up as part of the post inspection monitoring process.

‘Other’ areas of practice that requires improvement

Areas of practice that requires improvement is any area of practice, which cannot be classified as either a ‘critical’ or ‘major’ area of non compliance, but which indicates a departure from statutory requirements or good practice.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
None			

Additional information from the Person Responsible